Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in January 2006.

New Approvals

ANADA Number: 200-334

Pioneer Product: 091-818
Trade Name: EQUIZONE 100™
Ingredients: Phenylbutazone
Sponsor: A & G Pharmaceuticals, Inc.
Approval Date: November 18, 2005
Status: Prescription only
Route: Oral
Species: Horses
Drug Form: Powder
Concentration: 1 gram of phenylbutazone per 10 grams of powder
Indications: For the relief of inflammatory conditions associated with the musculoskeletal system.

21CFR 520.1720e & 510.600

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 095-735

Trade Name: Rumensin® 80 Type A Medicated Article
Ingredients: Monensin sodium
Sponsor: Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date: November 18, 2005

This application provides for a change in the species class from pasture cattle (stocker and feeder cattle and dairy and beef replacement heifers) to growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

21CFR 558.355

NADA Number: 095-735

Trade Name: Rumensin® 80 Type A Medicated Article
Ingredients: Monensin sodium
Sponsor: Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date: December 15, 2005

This application provides for use of monensin Type C medicated feeds in component feeding systems (including top dress) for increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

21CFR 558.355

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 140-883

Trade Name: Legend® Multi Dose
Ingredients: Hyaluronate sodium
Sponsor: Bayer Healthcare LLC, Animal Health Division
Approval Date: December 15, 2005

This application provides for the use of this hyaluronate sodium solution, formulated with benzyl alcohol preservative, from a multi-dose vial for intravenous administration to horses.

21CFR 522.1145

Addition of Sponsor

A & G Pharmaceuticals, Inc.
1030 West Commodore Blvd.
Jackson, NJ 08527

Labeler code: 057699

Technical Amendment

In Title 21 of the Code of Federal Regulations, parts 500 to 599, revised as of April 1, 2005, on page 46, in Sec. 510.600, paragraph (c)(1), the entry for ``Intervet, Inc." is corrected by adding ``Millsboro, DE 19966" at the end of the entry.

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (123) entitled ``Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals", [Docket No. 2004D-0468]. This guidance provides recommendations regarding the development of target animal safety and effectiveness data to support approval of veterinary non-steroidal anti-inflammatory drugs (NSAIDs), specifically cyclooxygenase (COX) inhibitors.

Submit written or electronic comments on agency guidances at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments on the guidance should be identified with the full title of the guidance and the docket number found in brackets at the start of this notice.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

For further information contact: Linda Wilmot, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0135, e-mail: lwilmot@cvm.fda.gov.

The Food and Drug Administration (FDA) is announcing the availability for comments of a draft revised guidance for industry (92) entitled ``Impurities in New Veterinary Drug Substances (Revision)" VICH GL10(R), [Docket No. 1999D-2215] (formerly 99D-2215). This draft revised guidance, which updates a final guidance on the same topic for which a Notice of Availability was published in the Federal Register of July 7, 2000 (the 2000 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The draft revised document is intended to provide guidance for registration applicants on the content and qualification of impurities in new veterinary drug substances produced by chemical syntheses and not previously registered in a country, region, or member state.

Submit written or electronic comments by February 3, 2006 to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time. Comments should be identified with the full title of the draft revised guidance and the docket number. Submit written comments on the draft revised guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

For further information contact: Dennis Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dbensley@cvm.fda.gov.

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (166) entitled ``Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)--Phase II" (VICH GL38) [Docket No. 2004D-0156]. This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document provides recommendations for internationally harmonized test methods used to generate environmental fate and toxicity data.

Submit written or electronic comments on agency guidances at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number found in brackets at the start of this notice.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

For further information contact: Charles E. Eirkson, Center for Veterinary Medicine (HFV-145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6958, e-mail: ceirkson@cvm.fda.gov.

The Food and Drug Administration (FDA) is announcing the availability for comments of a draft revised guidance for industry (93) entitled ``Impurities in New Veterinary Medicinal Products (Revised)" VICH GL11(R) [Docket No. 1999D-2145] (formerly 99D-2145). This draft revised guidance, which updates a final guidance on the same topic for which a notice of availability was published in the Federal Register of July 7, 2000 (the 2000 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised document is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States. The revised guidance addresses only those impurities in new veterinary medicinal drug products classified as degradation products.

Submit written or electronic comments by February 9, 2006, to ensure their adequate consideration in preparation of the final guidance document. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft revised guidance and the docket number found in brackets at the start of this notice. General comments on agency guidance documents are welcome at any time.

Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

For further information contact: Dennis Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dbensley@cvm.fda.gov.

The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the United States Food and Drug Administration, Department of Health and Human Services and the Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia. This MOU is intended to establish an information-sharing arrangement between APVMA and FDA. The Participants intend to strengthen the exchange of knowledge and expertise to enhance the efficiency and effectiveness of their respective roles. This MOU focuses on cooperation in relations to the operational aspects of animal drug regulation and is not intended to cover broader government regulatory policy or to cover areas not falling under the common jurisdictional purview of the Participants. The agreement became effective October 20, 2005.

For further information contact: Matthew E. Eckel, Office of International Programs, Food and Drug Administration, 5600 Fishers Lane (HFG-1), Rockville MD, 20857, 301-827-4480, FAX 301-480-0716.